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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,473	11/08/2001	Michael Hagen	33,482-00	3152
25291	7590	10/18/2005	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			LE, EMILY M	
		ART UNIT	PAPER NUMBER	
		1648		

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/009,473	HAGEN, MICHAEL
Examiner	Art Unit	
Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 06/27/05+07/18/05.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) See Continuation Sheet is/are pending in the application.  
 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 88-90, 98, 105, 109, 116-119, 160, 163-164 and 167 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are 88-90,98-119,127-130,138-141,149-152,160,162-164,166-168,170,171,173,174,176-180,182,183 and 185.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 99-104,106-108,110-115,127-130,138-141,149-152,162,166,168,170,171,173,174,176,177,179,180,182,183 and 185.

## DETAILED ACTION

### ***Status of claims***

1. Claims 1-87, 91-97, 120-126, 131-137, 142-148, 153-159, 161, 165, 169, 172, 175, 181 and 184 are cancelled.

Claims 88-90, 98-119, 127-130, 138-141, 149-152, 160, 162-164, 166-168, 170-171, 173-174, 176-180, 182-183 and 185 are pending.

Claims 99-104, 106-108, 110-115, 127-130, 138-141, 149-152, 162, 166, 168, 170-171, 173-174, 176-177, 179-180, 182-183 and 185 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/21/2004 and 01/28/05.

Claims 88-90, 98, 105, 109, 116-119, 160, 163-164 and 167 are under examination.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 98, 105, 109, 116-119, 160, 163-164 and 167 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As set forth in the previous office action: Regarding the above listed claims, the phrase "derived from" renders the claim(s) indefinite because one skilled in the art would not be able to reasonably ascertain the scope of the cited limitation.

In response to the above-summarized rejection, Applicant traversed the rejection, while asserting that the rejection is improper. Applicant submits that one of skill in the art understands that antigens may be obtained from biological sources such as bacteria, viruses, tumor cells or fungi by many alternative methods. It is well known in the art that the protein may be directly purified from the pathogen itself or from cells infected with the pathogen or in the case of tumors, from the tumor cells. One of skill in the art also understands that rather than purify the protein directly from infected cells, the gene encoding the antigen may be cloned and expressed in a more convenient culture system. Therefore, the "derived from" language serves as a well understood shorthand to reciting well-known steps. Applicant also submits that the Office has regularly accepted the phrase "derived from", as exemplified by claim 9 of U.S Patent No. 6544518. Since one of skill in the art would indeed understand the meaning of "derived from" and the Office regularly accepts such terminology, Applicant submits that the rejection is improper and should be withdrawn.

Applicant's submission has been considered, however, it is not found persuasive. Applicant is reminded that each patent application is treated on its own merits, not of other patent applications or issued patents. Ergo, Applicant's latter submission is moot.

Regarding Applicant's other submission, whereby one of skill in the art would indeed understand the meaning of "derived from", in the instant, the Examiner is one of skill in the art, yet, the Examiner cannot envision the metes and bounds of the language "derived from". In the absence of boundaries that are discernible, the claims are rendered indefinite.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 88-90 are rejected under 35 U.S.C. 102(a) as being anticipated by Boon et al., WO 9857659, in view of Morein et al.<sup>1</sup>

In response to the rejection set forth in the previous office action, Applicant amends the transitional term from comprising to "consisting of", and added the limitation "together with a diluent or carrier". In addition, Applicant submits the following:

Boon et al. are concerned with identifying the cytokine that would best augment the already known adjuvant combination of MPL and the saponin QS-21 combination that contains IL-12, MPL, and QS-21. Boon et al. do not teach or suggest adding IL-12 to MPL in the absence of QS-21. Nor do Boon et al. teach that GM-CSF is a possible component of the adjuvant combination. Rather, Boon et al. teach that GM-CSF was "unable to enhance the effect of the QS21/MPL adjuvant". Consequently, since every element of the presently claimed invention is not identically shown in Boon et al., the claimed invention cannot be anticipated by this reference. Applicant therefore requests that this rejection be withdrawn.

Applicant's submission has been considered, however, it is not found persuasive. Applicant is correct to note that Boon et al. does teach an adjuvant combination of IL-12, MPL, and QS-21, and that Boon et al. do not teach or suggest adding IL-12 to MPL

in the absence of QS-21. However, Applicant is reminded that the claims recite a composition consisting of an antigen, 3D-MPL, GM-CSF or IL-12, and a diluent or a carrier.

In the instant, Boon et al. teaches all the limitations that are recited in the claims. Boon et al. teaches a composition consisting of an antigen, 3D-MPL, IL-12, and a carrier. The carrier that Boon et al. teaches is QS-21. QS-21 is a saponin. Saponins are recognized in the art as a pharmaceutical carrier, as evidenced by Morein et al. [Abstract of Morein et al.] Ergo, Boon et al. teaches a composition consisting of an antigen, 3D-MPL, IL-12, and a carrier. Thus, Boon et al. continues to anticipate the claimed invention.

Furthermore, contrary to Applicant's assertion that Boon et al. does not teach that GM-CSF is a possible component of the adjuvant combination, Boon et al. does teach a composition comprising an antigen, 3D-MPL, GM-CSF, and a carrier. Though this teaching is not directly expressed by Boon et al., it is implicitly or inherently expressed by Boon et al. Boon et al. teaches that the GM-CSF and QS21/MPL combination did not enhance the effect of the QS21/MPL adjuvant. In the instant, in order to arrive at such conclusion, Boon et al. would have necessarily had the composition. Thus, Boon et al. does teach a composition comprising an antigen, 3D-MPL, GM-CSF, and a carrier.

In the instant, while it is readily apparent that Boon et al. anticipates the invention that was previously claimed, however, in view of the amendment that Applicant presented, and because the exact ingredients that is used by Boon et al. cannot be

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<sup>1</sup> Morein et al. U.S. Patent No. 5603958

readily ascertained, the Office will not insist that Boon et al. teaches a composition consisting of an antigen, 3D-MPL, GM-CSF, and a carrier.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 98, 116-117 and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon et al., WO 9857659, as applied to claims 88 and 90.

In response to the rejection set forth in the previous office action, Applicant traversed the rejection, while submitting the same remarks as those summarized in the claim rejections-35 USC § 102 section of the instant office action, above. In addition to above, Applicant also submits that Boon et al. clearly fail to appreciate and describe the useful two-adjuvant combination of the present invention.

Applicant's submission has been considered, however, it is not found persuasive. Applicant is correct to note that Boon et al. does teach an adjuvant combination of IL-12, MPL, and QS-21, and that Boon et al. do not teach or suggest adding IL-12 to MPL in the absence of QS-21. However, Applicant is reminded that the claims recite a composition consisting of an antigen, 3D-MPL, GM-CSF or IL-12, and a diluent or a carrier.

In the instant, Boon et al. teaches all the limitations that are recited in the claims. Boon et al. teaches a composition consisting of an antigen, 3D-MPL, IL-12, and a carrier. The carrier that Boon et al. teaches is QS-21. QS-21 is a saponin. Saponins

are recognized in the art as a pharmaceutical carrier, as evidenced by Morein et al. [Abstract of Morein et al.] Ergo, Boon et al. teaches a composition consisting of an antigen, 3D-MPL, IL-12, and a carrier. Ergo, the claimed invention is unpatentable over Boon et al.

Applicant is reminded that Boon et al. does not need to appreciate or describe the usefulness of the claimed invention the same way as Applicant has to render the claimed invention unpatentable. The Boon et al. solely need to teach the invention as claimed.

Furthermore, contrary to Applicant's assertion that Boon et al. does not teach that GM-CSF is a possible component of the adjuvant combination, Boon et al. does teach a composition comprising an antigen, 3D-MPL, GM-CSF, and a carrier. Though this teaching is not directly expressed by Boon et al., it is implicitly or inherently expressed by Boon et al. Boon et al. teaches that the GM-CSF and QS21/MPL combination did not enhance the effect of the QS21/MPL adjuvant. In the instant, in order to arrive at such conclusion, Boon et al. would have necessarily had the composition. Thus, Boon et al. does teach a composition comprising an antigen, 3D-MPL, GM-CSF, and a carrier.

In the instant, while it is readily apparent that Boon et al. anticipates the invention that was previously claimed, however, in view of the amendment that Applicant presented, and because the exact ingredients that is used by Boon et al. cannot be readily ascertained, the Office will not insist that Boon et al. teaches a composition consisting of an antigen, 3D-MPL, GM-CSF, and a carrier.

7. Claims 105, 109, 160, 163-164 and 167 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon et al., WO 9857659, as applied to claims 88, 98 and 116.

In response to the rejections set forth in the previous office action, Applicant traversed the rejection, Applicant amends the transitional term from comprising to "consisting of", and added the limitation "together with a diluent or carrier". In addition, Applicant submits the following:

Boon et al. discloses an adjuvant composition comprising not less than three adjuvants: a saponin adjuvant, monophosphoryl lipid A or a derivative thereof, and IL-12. The composition of Boon et al. would not contain GM-CSF because they found that it was unable to enhance the effect of the QS21/MPL adjuvant". Therefore, the skilled artisan who combines the adjuvant composition of Boone et al. with an antigen to elicit an immune response or cytotoxic T lymphocyte responses would not arrive at the claimed invention.

Applicant's submission has been considered, however, it is not found persuasive. Applicant is correct to note that Boon et al. does teach an adjuvant combination of IL-12, MPL, and QS-21, and that Boon et al. do not teach or suggest adding IL-12 to MPL in the absence of QS-21. However, Applicant is reminded that the claims recite a composition consisting of an antigen, 3D-MPL, GM-CSF or IL-12, and a diluent or a carrier.

In the instant, Boon et al. teaches all the limitations that are recited in the claims. Boon et al. teaches a composition consisting of an antigen, 3D-MPL, IL-12, and a carrier. The carrier that Boon et al. teaches is QS-21. QS-21 is a saponin. Saponins are recognized in the art as a pharmaceutical carrier, as evidenced by Morein et al.

[Abstract of Morein et al.] Ergo, Boon et al. teaches a composition consisting of an antigen, 3D-MPL, IL-12, and a carrier. Ergo, the claimed invention is unpatentable over Boon et al.

Furthermore, contrary to Applicant's assertion that Boon et al. does not teach that GM-CSF is a possible component of the adjuvant combination, Boon et al. does teach a composition comprising an antigen, 3D-MPL, GM-CSF, and a carrier. Though this teaching is not directly expressed by Boon et al., it is implicitly or inherently expressed by Boon et al. Boon et al. teaches that the GM-CSF and QS21/MPL combination did not enhance the effect of the QS21/MPL adjuvant. In the instant, in order to arrive at such conclusion, Boon et al. would have necessarily had the composition. Thus, Boon et al. does teach a composition comprising an antigen, 3D-MPL, GM-CSF, and a carrier.

In the instant, while it is readily apparent that Boon et al. anticipates the invention that was previously claimed, however, in view of the amendment that Applicant presented, and because the exact ingredients that is used by Boon et al. cannot be readily ascertained, the Office will not insist that Boon et al. teaches a composition consisting of an antigen, 3D-MPL, GM-CSF, and a carrier.

8. Claim 118 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boon et al., WO 9857659 in view of Haynes et al., U.S Patent No. 5993819, as applied to claims 88, 98 and 116-117 above.

In response to the rejection set forth in the previous office action, Applicant submits that the skilled artisan would have fallen short of obtaining the claimed invention: an antigenic composition consisting of the HIV peptide having SEQ ID NO: 2

together with a specific two-adjuvant composition. Thus, the claimed invention is not obvious over the teaching of Boon et al. and Haynes.

Applicant's submission has been considered, however, it is not found persuasive. Contrary to Applicant's assertion, Boon et al. does teach an antigenic composition consisting of an antigen together with a specific two-adjuvant composition.

In the instant, Boon et al. teaches all the limitations that are recited in the claims. Boon et al. teaches a composition consisting of an antigen, 3D-MPL, IL-12, and a carrier. The carrier that Boon et al. teaches is QS-21. QS-21 is a saponin. Saponins are recognized in the art as a pharmaceutical carrier, as evidenced by Morein et al. [Abstract of Morein et al.] Ergo, the claimed invention is unpatentable over Boon et al. in view of Haynes.

### ***Conclusion***

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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